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10/721,115	11/24/2003	John G. Sotos	APN-001	6156

7590  
Kenneth M. Kaslow  
c/o Apneos Corporation  
#41  
2033 Ralston Ave.  
Belmont, CA 94002

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/721,115

Applicant(s)

SOTOS ET AL.

Examiner

Patricia C. Mallari

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

The amendments to the specification submitted 7/10/06 are considered to be non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment to be compliant, amendments to the specification must be made by adding, deleting, or replacing a paragraph or section, wherein a section is defined as set forth in CFR 1.77(b), or by a substitute specification. For example, in the instruction numbered "2", three paragraphs should be presented, including a replacement paragraph for paragraph 3, the new paragraph, and the paragraph following the new paragraph. The applicants are required to correct all instances of such amendment to the specification in order for the amendments to the specification to be entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-13, 15-19, 21, 29, 31-37, 39-47, 49, and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,514,218 to Yamamoto.

Yamamoto teaches a system for monitoring a patient comprising a vibration sensor (microphone) 3 for collecting tracheal vibration information from the patient and position sensor 7 that changes state depending upon its orientation with respect to the earth's gravity, at least a portion of which is substantially adjacent to a portion of the vibration sensor (see entire document, especially figs. 1, 4, 6a-6c; col. 3, line 60-col. 4, line 5; col. 4, lines 42-49; col. 6, lines 40-65; col. 7, line 55-col. 8, line 62 of Yamamoto).

Regarding claims 2, 36, and 37, the vibration sensor is coupled near a tracheal segment of the patient see entire document, especially (figs. 1 & 16; col. 4, lines 42-45 of Yamamoto).

Regarding claims 4-11, 15-17, 39-47, the position sensor 7 comprises first and second gravity sensing switches 71a, 71b having at least one axis of orientation with respect to gravity such that the switch occupies different states depending upon which end of the axis is closer to gravity source (see entire document, especially figs. 6a-6c, 7a; col. 7, line 10-col. 9, line 21 of Yamamoto). With further regard to claims 6-11, 15, 16, and 41-47 first gravity sensing switch 71a has a first axis of orientation with respect to gravity and second gravity sensing switch 71b has a second axis of orientation with respect to gravity which can be superposed at an angle to the first axis (see entire document, especially fig. 6a; 7a of Yamamoto).

With further regard to claims 5 and 47, the gravity sensing switch comprises a tilt switch having a body 75 containing a cavity, a plurality of contact point pairs 77a-d 78a-d within the cavity, and an electrically conductive material 76 that is able to move within the cavity, such that as the orientation of the body with respect to gravity changes,

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different pairs of contact points are connected, thus providing a signal indicative of the tilt switch's orientation with respect to gravity (see entire document, especially figs. 6b & 6c; col. 7, lines 22-54 of Yamamoto).

With further regard to claims 7-13, and 15-17 housing 51, belts 52, 53, and adhesive tape couple the system to at least a portion of the patient's body, such that the position sensor provides information indicative of changes in orientation of the portion of the patient's body to which the system is coupled (see entire document, especially figs. 1, 4; col. 4, lines 42-44; col. 5, lines 23-30 of Yamamoto).

Also regarding claims 8-11, 15, 16, and 42, a plane containing a superposition of the two axes is at least at an angle to the portion of the patient's body such that the position sensor provides information indicative of which of at least two positions the body portion is in with respect to the earth's gravity (see entire document, especially fig. 4, 6a, 7a of Yamamoto). With further regard to claims 9-11, 15, and 16 a housing 5 is coupled to an axial portion of the patient's body (see entire document, especially figs. 1, 4, 6a, 7a of Yamamoto). With further regard to claims 10 and 11, the angle between the two superposed axes is substantially a right angle (see entire document, especially figs. 6a, 7a; col. 9, lines 17-21 of Yamamoto). With further regard to claim 11, the angle between the plane and the axial portion of the patient's body is substantially a right angle, as shown in figure 4 of Yamamoto.

With further regard to claims 13 and 46, a housing 51 contains at least a portion of the vibration sensor and a portion of the position sensor (see entire document,

especially fig. 16; col. 14, lines 32-40 of Yamamoto), wherein the relay cable 12 and relay unit 6 also constitute a portion of the vibration sensor.

With further regard to claims 15-17, 40, and 43-45, the angle between the superposed axes of the two gravity sensing switches and the angle between the plane and the axial portion of the patient's body are such that the switches indicate which of at least two positions the axial portion of the patient is in, the indicated positions including substantially supine, substantially prone, substantially left lateral decubitus, and substantially right lateral decubitus (see entire document, especially col. 7, line 66-col. 8, line 61 of Yamamoto).

Regarding claims 18, 19, 21, 29, 33-35, 49, and 50 recording means records tracheal vibration information and data representing the state of the position sensor or orientation of the body portion over time (see entire document, especially col. 10, line 66-col. 11, line 38 of Yamamoto). With further regard to claim 21, the recording means further comprises a memory 89, a power source 80, conversion means 88 for receiving and digitizing the tracheal vibration information and information indicative of the orientation of the patient's body, and means 90 for writing the digital data into the memory (see entire document, especially col. 10, line 66-col. 11, line 38 of Yamamoto). With further regard to claim 19, a computing device 90 reads and performs calculations on the recorded data (see entire document, especially col. 11, line 31-col. 12, line 32 of Yamamoto). With further regard to claim 50, the memory is non-volatile memory and is coupled to the patient such that the patient may be in a state of diminished

consciousness without being disturbed during the period of diminished consciousness (see entire document, especially figs. 1 & 16; col. 11, lines 30-44 of Yamamoto).

Regarding claims 31-37, 39-47, 49, and 50 the description of the apparatus of Yamamoto inherently discloses a method of using such apparatus.

Regarding claim 35, the data is recorded during a period of time associated with diminished consciousness of the patient (see entire document, especially col.2, lines 4-19; col. 8, lines 4-61 of Yamamoto).

Claims 1-4, 6-9, 12, 15, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,263,491 to Thornton (herein referred to as Thornton '491). Thornton '491 teaches a system for monitoring a patient comprising a vibration sensor (microphone) M1 and a position sensor 16, SW1, SW2 that changes state depending on its orientation with respect to the earth's gravity, at least a portion of which is substantially adjacent to a portion of the vibration sensor (see entire document, especially fig. 1; col. 2, line 56-col. 3, line12 of Thornton '491).

As to the language "for collecting tracheal vibration information from the patient", the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Thornton '491 teaches all of the claimed structural limitations and their recited relationships. The microphone of Thornton '491, is certainly capable of collecting tracheal vibration information, especially in light of the applicants' disclosure that the vibration sensor is merely a microphone.

Regarding claim 3, the position sensor 16 comprises an accelerometer (see entire document, especially col. 2, line 59 of Thornton '491).

Regarding claims 4, 6-9, and 16 the position sensor comprises a gravity sensing switches SW1, SW2 having at least one axis of orientation with respect to gravity such that the switch occupies different states depending on which end of the axis is closer to the source of gravity (see entire document, especially col. 2, lines 62-54; col. 4, lines 37-50 of Thornton '491; also see col. 2, lines 52-57; col. 3, lines 21-35 of US Patent No. 4,830,021). With further regard to claim 6, first switch SW1 has a first axis of orientation with respect to gravity and a second switch SW2 has a second axis of orientation with respect to gravity, which can be superposed at an angle to the first axis (see entire document, especially fig. 1 of Thornton '491).

With further regard to claims 7-9, 12, 15, and 17 adhesive and a belt (or collar) are used to couple the system to at least a portion of the patient's body, such that the position sensor 16, SW1, SW2 provides information indicative of changes in orientation of the portion of the patient's body to which the system is coupled (see entire document, especially fig. 1; col. 2, lines 59-66; col. 4, lines 18-20; col. 5, lines 51-69 of Thornton '491). With further regard to claim 8, a plane containing a superposition of the first axis and the second axis is at an angle to the patient's body portion to which the system is coupled such that the position sensor provides information indicative of which of two or more positions the portion of the patient's body is in with respect to the earth's gravity (see entire document, especially fig. 1; col. 5, lines 51-69 of Thornton '491).



With further regard to claim 9, a housing, shown as reference numeral 12 in figure 1 of Thornton '491, is adapted to be coupled to an axial portion of the patient's body.

With further regard to claims 15 and 17, the angle between the superposed axes and the angle between the plane and the axial portion of the patient's body are such that the tilt switches indicate which of two or more positions the axial portion of the patient's body is in, one of which positions is substantially supine (lying down) and one of which positions is not substantially supine (see entire document, especially col. 4, lines 42-44 of Thornton '491).

Regarding claims 18 and 19, the applicants should note that the language "for recording data representing the tracheal vibration" is merely "intended use" language which cannot be relied upon to define over the prior art, since Thornton '491 teaches all of the claimed structural limitations and their recited relationships. The recording means 12 of Thornton '491 is certainly capable of recording any information (see entire document, especially col. 3, lines 38-52 of Thornton '491).

Claims 1, 2, 4, 5, 12-14, 17-19, 21, 25, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,275,159 to Griebel. Griebel discloses a system for monitoring a patient comprising a vibration sensor (microphone) 4, 16, 17 for collecting tracheal vibration information from the patient and a position sensor 6, 22 that changes state depending upon its orientation with respect to the earth's gravity, at least

a portion of which is substantially adjacent to a portion of the vibration sensor (see entire document, especially figs. 1 & 2; col. 5, lines 30-38; col. 6, lines 5-22 of Griebel).

Regarding claims 4, 5, and 17, the position sensor 6 comprises a gravity sensing switch having at least one axis of orientation with respect to gravity such that the switch occupies different states depending upon which end of the axis is closer to the source of gravity (see entire document, especially col. 6, lines 5-22 of Griebel). With further regard to claim 5, the switch further comprises a tilt switch having a body containing a cavity, a plurality of contact point pairs within the cavity, and an electrically conductive material that is able to move within the cavity, such that, as the orientation of the body with respect to gravity changes, different pairs of contact points are connected, thus providing a signal indicative of tilt switch's orientation with respect to gravity (see entire document, especially col. 6, lines 8-17 of Griebel). With further regard to claim 17, housing 2 and adhesive serve as means for simultaneously coupling the system to an axial portion of the patient's body with the axis of the gravity sensing switch at an angle to the axial portion such that the tilt switch provides information indicative of which of two or more positions the axial portion of the patient's body is in, one of which is substantially supine and one of which is not substantially supine (see entire document, especially fig. 2; col. 6, lines 5-22 of Griebel).

Regarding claim 12-14 and 30, straps 24, 25, housing 2, and adhesive serve as means for simultaneously coupling at least a portion of the vibration sensor and a portion of the position sensor to portion of the patient's body, such that the position sensor tracks changes in orientation of the body portion to which the system is coupled

(see entire document, especially fig. 2; col. 5, lines 32-38; col. 6, lines 5-7 of Griebel).

With further regard to claims 13 and 14, a housing contains at least a portion of each of the vibration sensor and position sensor, wherein housing 2 contains the position

analyzer 22 portion of the position sensor and the filter and amplifier 16, 17, portions of the vibration sensor, and the hollow tetrahedron of the position pickup further comprises another portion of the housing (see entire document, especially figs. 2 & 5; col. 6, lines 5-17; col. 6, lines 40-57; col. 7, lines 10-13 of Griebel). With further regard to claim 14,

adhesive material is coupled to a portion of the housing (see entire document, especially col. 6, lines 5-8 of Griebel). With further regard to claim 30, the housing bears an indicator means for showing the orientation the housing is to have when coupled to the body (see entire document, especially col. 6, lines 5-8 of Griebel).

Regarding claims 18, 19, 21, and 25, a recording means records tracheal vibration information data and the state of the position sensor data over time or data indicative of the orientation of the portion of the patient's body to which the system is coupled over time (see entire document, especially col. 6, lines 23-36; col. 7, lines 14-27 of Griebel). With further regard to claim 21, the recording means further comprises a memory, power source, conversion means for digitizing the tracheal vibration information and information indicative of the orientation of the patient's body, and means for writing the digital data into the memory (see entire document, especially col. 6, lines 32-36 and lines 55-57; col. 7, lines 10-29 of Griebel). With further regard to claim 25, a playback means is capable of substantially recreating the collected tracheal

vibration information from the recording means (see entire document, especially fig. 6; col. 7, lines 52-69 of Griebel).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto, as applied to claims 1, 2, 4-13, 15-19, 21, 29, 31-37, 39-47, 49, and 50 above, and further in view of US Patent No. 6,241,683 to Macklem et al. Yamamoto is silent as to the details of sampling the tracheal vibration information. However, Macklem teaches sampling tracheal vibration information at a rate of 3000 Hz (see entire document, especially col. 6, lines 2-16 of Macklem), a rate that is at least 2 kHz. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the sampling rate of Macklem in the system of Yamamoto, since Yamamoto teaches measuring and recording tracheal vibration information and Macklem discloses 3000 Hz as an appropriate sampling rate for measuring and recording such information.

Claim 22 is rejected under 35 U.S.C 103(a) as being unpatentable over Yamamoto, as applied to claims 1, 2, 4-13, 15-19, 21, 29, 31-37, 39-47, 49, and 50 above, and further in view of US Patent No. 6, 551,252 to Sackner et al. Yamamoto is silent as to the capacity of the memory in terms of megabytes (MB). However, Sackner teaches an ambulatory monitoring system comprising a recording means having a memory capable of storing 128 MB for 24 hours worth of data (see entire document, especially col. 18, lines 3-39 of Sackner), wherein such a memory is also capable of storing 32 MB of data. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a memory capable of storing 128 MB of data in the system of Yamamoto, since Yamamoto teaches a recording means in an ambulatory monitoring system that has a memory capable of storing data for 24 hours, and Sackner teaches a memory of 128 MB is of sufficient size to store 24 hours worth of data in an ambulatory system.

Claims 24 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto, as applied to claims 1, 2, 4-13, 15-19, 21, 29, 31-37, 39-47, 49, and 50 above, and further in view of US Patent No. 6,432,061 to Nissilä et al. Yamamoto teaches lacks a wireless transmitter and receiver. However, Nissilä teaches a patient monitoring system wherein the sensor 7 may be connected to the recording means 9 by either a wired connection 21 or wireless connection 22, the wireless connection 22 comprising a wireless transmitter 22a and receiver 22b (see entire document, especially figs. 2 & 3; col. 4, lines 15-44 of Nissilä). In the wireless embodiment, the signals are

converted to digital data before transmission (see entire document, especially fig. 5 of Nissilä). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a wireless connection, as described by Nissilä in place of the wired connection between the sensor and recording means of Yamamoto, since Nissilä teaches the two means of connection as being functionally equivalent means for transmitting data from a sensor to a recording means.

Claims 23 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto as applied to claims 1, 2, 4-13, 15-19, 21, 29, 31-37, 39-47, 49, and 50 above, and further in view of US Patent No. 6,168,568 to Gavriely. Yamamoto lacks a wireless transmitter and transceiver. However, Gavriely teaches a system in which either a wired or wireless microphone may be used to measure tracheal sounds or vibrations, wherein, when a wireless microphone is used, data representing tracheal vibrations is sent to a wireless remote receiver prior to digitizing the signals (see entire document, especially figs. 1, 3-5; col. 15, lines 9-45 of Gavriely). Therefore, it would have been obvious to one of ordinary skill in the art to use a wireless receiver and transmitter in place of the wired connection of Yamamoto, since Gavriely teaches wired and wireless connections as being functionally equivalent means of data communication.

Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto as applied to claims 1, 2, 4-13, 15-19, 21, 29, 31-37, 39-47, 49, and 50

above, and further in view of US Patent No. 6,168,568 to Gavriely. Yamamoto is silent as to the frequency response of the microphone for sensing tracheal vibrations and lacks a playback device. However, Gavriely teaches a patient monitoring system wherein tracheal sounds or vibrations are measured using a microphone have a frequency response of 75-2000 Hz (see entire document, especially figs. 1-5; col. 11, lines 14-16; col. 12, lines 32-42 of Gavriely), or at least approximately 400 to 100 Hz. Gavriely further teaches a playback means 14 further comprising a sound output device 24 (see entire document, especially fig. 1; col. 11, line 51-col. 12, line 15 of Gavriely). The device 24 is capable of reproducing sound (see entire document, especially col. 11, lines 51-col. 12, line 7 of Gavriely), wherein any reasonable output from the output device 24 would be of at least approximately the same frequency range of the frequency response at the microphone and sound substantially the same as listening through a listening device at the position of the microphone at the time of collection the tracheal vibration information. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the microphone of Gavriely as that of Yamamoto, since Yamamoto teaches using a microphone to detect tracheal vibrations, and Gavriely describes an appropriate such microphone. It would further have been obvious to combine the playback means of Gavriely with the system of Yamamoto in order to allow simultaneous auscultation and visual monitoring of breath sounds, for example (see entire document, especially col. 12, lines 1-7 of Gavriely).

Claims 38 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Thornton '491. Karakasoglu teaches a method for monitoring a patient wherein tracheal vibration information is collected from a patient at a location on the patient's body by coupling a vibration sensor to the patient (see entire document, especially col. 5, lines 34-38; figs. 1 & 2 of Karaksoglu), and information indicative of the orientation of a portion of the patient's body is obtained substantially adjacent to the location at which the tracheal vibration information is collected (see entire document, especially fig. 1; col. 5, lines 28-30 of Karaksoglu). Karakasoglu is silent as to the details of the body position sensor S7.

However, Thornton '491, as described above, teaches a position sensor comprising an accelerometer 16 and gravity sensing switches SW1 and SW2, the position sensor changing state depending upon its orientation with respect to gravity (see entire document, especially col. 2, lines 59-66; col. 4, lines 38-63; col. 5, lines 30-69 of Thornton '491). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the position sensor of Thornton '491 as that of Karaksoglu, since Karaksoglu teaches using a position sensor, and Thornton '491 describes an appropriate such position sensor.

Regarding claims 41-43, the position sensor comprises a first gravity sensing device SW1 having a first axis of orientation with respect to gravity and a second gravity sensing device SW2 having a second axis of orientation with respect to gravity which can be superposed at an angle to the first axis (see entire document, especially col. 2, lines 62-54; col. 4, lines 37-50 of Thornton '491; also see col. 2, lines 52-57; col. 3, lines



21-35 of US Patent No. 4,830,021). With further regard to claim 42, the gravity sensing devices SW1 and SW2 are coupled to an axial portion of the patient's body with a plane containing a superposition of the two axes at an angle to an axial portion of the patient's body such that the states of gravity sensing devices provide information indicative of which of two or more positions the axial portion of the patient's body is in (see entire document, especially fig. 1; col. 4, lines 37-50; col. 5, lines 51-68 of Thornton '491). With further regard to claim 43, the angle between the two axes and the angle between the plane containing the devices SW1 and SW2 and the axial portion of the patient's body is such that the states of the gravity sensing devices SW1 and SW2 provide information to indicate whether the patient is substantially supine or not substantially supine (see entire document, especially fig. 1; col. 4, lines 37-50 of Thornton '491).

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto, as applied to claims 1, 2, 4-13, 15-19, 21, 29, 31-37, 39-47, 49, and 50 above, and further in view of US Patent No. 6,949,475 to Hatlesad. Yamamoto fails to teach using an accelerometer as a first gravity sensing device. However, Hatlesad teaches that either an accelerometer or tilt switch to sense patient posture (see entire document, especially col. 5, lines 5-26; col. 7, lines 45-56 of Hatlesad). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use an accelerometer as the first gravity sensing device in place of the tilt sensor of Yamamoto, since Hatlesad teaches an accelerometer and a tilt sensor as being functionally equivalent means of sensing posture.

### ***Response to Arguments***

Applicant's arguments filed 7/10/06 have been fully considered but they are not persuasive.

With regard to the Yamamoto reference, the applicants argue that no portion of position sensors 71a and 71 b is substantially adjacent to a portion of microphone 3. The examiner disagrees. Figure 1 shows the vibration sensor 3 and the position sensor, wherein the position sensor is housed in breathing effort detection unit 5 (see fig. 4 of Yamamoto), as being substantially adjacent to each other. The applicants have not set forth any special definition in the specification or guidelines in the claim language for "substantially adjacent". In its broadest reasonable interpretation, the phrase means close to each other to a considerable degree. The placement shown in figure 1 of Yamamoto shows the sensors close to each other to a considerable degree, especially with reference to the size of the person, or with reference to the size of a hospital or house in which the apparatus may be used. The applicants further state that and that Yamamoto fails to teach placement of the position sensors 7a and 71b superior to the level of the test subject's axillae. However, placement of the sensors superior to the subject's axillae is not set forth in any of the claims rejected as being anticipated by Yamamoto. Therefore, the rejection of claims as being anticipated by Yamamoto stands

With regard to the Thornton '491 reference, the applicants contend that the reference does not teach detection or use of tracheal vibration information, nor does it

suggest that the mastication microphone is capable of detecting tracheal vibration. In fact, the applicants state that the microphone is unable to detect tracheal vibrations because of the location of the microphone over the masseter muscle during use. However, the applicants should refer to the rejection above stating that the language "for collecting tracheal vibration information" is merely intended use. The microphone of Thornton '491 would definitely be capable of collecting such tracheal vibration if the location of the microphone were in a different position than over the masseter muscle. Therefore, the microphone of Thornton '491 is indeed *capable* or *for* collection of tracheal vibration information. The applicants also point out that the output of the microphone is filtered through a bandpass filter which would eliminate respiratory-related tracheal sounds. First of all, the applicants have not claimed "respiratory-related tracheal sounds", only "tracheal vibration". Secondly, the subsequent filtering of an output signal from the microphone fails to negate the fact that the microphone is indeed capable of acquiring/collecting the claimed tracheal vibrations. Therefore, rejections of claims as being anticipated by Thornton '491 also stand.

As to the applicant's arguments that the position sensor and vibration sensor of Griebel are not substantially adjacent, the applicants should refer to the examiner's comments above as to the interpretation of "substantially adjacent" set forth in regard to the applicants' comments on the Yamamoto reference. The examiner disagrees with the applicants' assessment that the position sensor 6 is not substantially adjacent to the vibration sensor 4. Both figures 1 and 2 show the sensors being substantially adjacent to each other. Therefore, rejection of claims as being anticipated by Griebel also stand.

The applicants arguments regarding rejections of claims under 35 U.S.C. 103(a) based on the Yamamoto reference in combination with at least one other reference merely hinge on at least one of the applicants' arguments set forth and addressed above. Since the examiner has shown how Yamamoto teaches all of the claimed limitations of the rejected claims, the rejection under 35 U.S.C. 103(a) based on Yamamoto and at least one other reference also stand.

With regard to the combination of Karaksoglu with Thornton, the applicants state that the position sensor and vibration sensors are not placed closed to each other. The applicants should refer to the examiner's interpretation of "substantially adjacent" set forth above. The applicants admit that Karaksoglu teaches the body position sensor S7 may be placed on the head and the vibration sensor S8 may be placed on the neck, wherein the neck and head are substantially adjacent locations. Karakasoglu does *not* teach away from placement of the two sensors in substantially adjacent positions. Therefore, rejection of claims as being unpatentable over Karaksoglu in view of Thornton stand.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

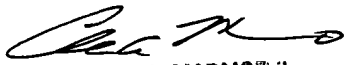
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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pcm

  
CHARLES A. MARMOR II  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700